FEB 25 2014

K130517

510(k) Summary
for
RH 3500 EZ transport Chair

1. SPONSOR

Harris Medical, LLC
8909 SE Marina Bay Dr.
Hobe Sound, FL 33455

Phone Number: 772-245-8361
Fax Number: 772-245-8361

Contact Person: Bud Harris

Date Prepared: February 25, 2013

2. Device Name

Proprietary Name: RH 3500 EZ Transport Chair,
Common/Usual Name: Wheelchair
Classification Name: Wheelchair, Mechanical
Regulation Number: 890.3850
Regulation Class: Class I
Product Code: IOR

3. PREDICATE DEVICES

Invacare Corp, Tracer Series, K9, K935398

Electro kinetic Technologies, Breez 1025, K111095

Barton Medical, model I-1000, K071793

4. DEVICE DESCRIPTION

The Harris Medical RH 3500 Transport Chair is a manually operated wheelchair that is propelled by human power. Its intended function and use is to provide mobility to a person limited to a sitting position. It may be used as an attendant propelled transport device in a healthcare environment such as a hospital, nursing home or extended care facility. The wheelchair consists primarily of an aluminum frame; 5 inch rear and front casters and handles for the wheelchair to be pushed. It

is a rigid or non-folding type of wheelchair that is designed for use by a patient weighing up to 250 lbs.

The frame is constructed of one inch (1) outside diameter Aluminum tube that is welded that has a wall thickness of 1/8 inch. The rear urethane wheels are fixed and front are urethane casters.

5. INTENDED USE

The RH 3500 EZ transport Chair is intended to transport patients within acute, alternative and long-term care facilities. The device can be operated indoors on carpeting, linoleum and other floors and on sidewalks. The RH 3500 EZ transport chair is controlled, steered and operated completely by a trained caregiver.

6. TECHNOLOGICAL CHARACTERISTICS

The RH 3500 is intended to be used by a trained caregiver that provides the human energy to operate the chair. The chair uses no other internal or external power source, such as battery power or AC power to perform any of its functions. The chair uses a foot pedal to activate the hydraulic pump to provide the pressure to rise and lower the chair. The hydraulic pressure causes the cylinder to move and activate the scissor jack up and down. This engineering approach has been used for many years to elevate various static objects such as cars, boats and people. The hydraulic system consists of a pump that is activated by a foot pedal, a hose, hydraulic piston (Cylinder) and a lever release or control value.

The technological characteristics of the RH 3500 EZ Transport Chair are very similar to the predicate devices, except the Breez 1025 and the I-1000 use electrical energy to operate the chair. This difference when compared to the RH 3500 raises no new safety issues. In fact the RH3500 has a lower technological risk than the cleared predicates because of a much simpler mechanical approach.

The frame material most commonly used for chairs (Wheel or Transport) is aluminum or steel and both have advantages, weight vs. cost. Both materials have a long history of meeting the design needs of the product life cycle. The wheels (Casters) used on the predicates and the RH3500 are similar in size, and the differences are acceptable.

The RH 3500 EZ transport chair has been tested with loads of 375 lbs. (50% overload) for periods of 24 hours with out any adverse events. The hydraulic system held without any position changes.

The RH 3500 is constructed from the following materials: Aluminum alloy 6063T for the frame. The casters have a capacity of 300lbs and made from steel and the wheels are grey non-marking injection molded rubber. The cover to the seat, back and leg rest is a 4 way stretch urethane knit fabric commonly used for this type of application.

7. SUBSTANTIAL EQUIVALENCE

The Harris Medical RH3500 EZ Transport Chair is substantially equivalent to Invacare Corporation manual wheelchairs (ALB19HBFR). The above device was granted marketing clearance by the FDA on March 1st 1994, under 510K number K 935398 and Electro kinetic Technologies K111095 and Barton Medical, K071793.

8. PERFORMANCE STANDARDS

No performance standards applicable to this device have been adopted under Section 514 of the Act.

The RH3500 passed a 24 hour sustained 50% overload test, a determination of strength. The results confirmed an allowable patient load of 250lbs.

The laterally, posteriorly and anteriorly tiltover test was performed on the RH3500 EZ transport chair as per the guidance document for mechanical wheelchairs. The conclusion drawn from this testing is that this chair is as safe as the predicate devices.

The materials used for the seat cover is a 4 way stretch urethane knit fabric and is certified by the manufacture to be fully compliant to the following: flame resistance Cal TB 117, Antibacterial AATCC 147-2004, Antifungal AATC 30-2004, and Non-irritant Draize Dermal Toxicity OECD testing #404, 2002.

The seat belt used meets the following Federal standard FMVSS209-302.

The RH3500 has been tested and passed in accordance with Annex A, B, C and E of ANSI/RESNA WC-4: 2012, Section 19: Wheelchairs used as Seats in Motor Vehicles.

Meets the requirements of ANSI/RESNA WC-1: 2009 section 15. Requirements for Information Disclosure Documentation and Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Harris Medical LLC
c/o James Wason, Ph.D.
Maelor Group, Inc.
7 Village Woods Drive
Amherst, NH 03031

Re: K130517
Trade/Device Name: RH 3500 EZ Transport Chair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: January 8, 2014
Received: January 10, 2014

Dear Dr. Wason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. .You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Peña -S

Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K130517

Device Name
RH 3500 EZ Transport Chair

Indications for Use *(Describe)*
The RH 3500 EZ Transport Chair is intended to transport patients within acute, alternative and long-term care facilities. The device can be operated indoors on carpeting, linoleum and other floors, and on sidewalks. The RH 3500 EZ Transport Chair is controlled, steered and operated completely by a trained caregiver.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos D. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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